IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

AQUESTIVE THERAPEUTICS, INC., Plaintiff, v. BIODELIVERY SCIENCES INTERNATIONAL, INC., Defendant.	Civil Action No. 5:19-CV-00505-D

INDIVIOR INC. *f/k/a* RECKITT BENCKISER PHARMACEUTICALS INC., and AQUESTIVE THERAPEUTICS, INC. *f/k/a* MONOSOL RX, LLC, Plaintiffs, v. BIODELIVERY SCIENCES INTERNATIONAL, INC., Defendant.	Civil Action No.: 5:15-cv-00350-D

AQUESTIVE'S MEMORANDUM OF LAW
IN SUPPORT OF ITS MOTION TO COMPEL DISCOVERY

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Pursuant to Federal Rules of Civil Procedure 26, 34, and 37 and Local Civil Rules 7.1 and 7.2, Plaintiff Aquestive Therapeutics, Inc. ("Aquestive") files this Memorandum of Law in support of its Motion to Compel Discovery from Defendant BioDelivery Sciences International Inc. ("BDSI").[1]

I. INTRODUCTION

It has been more than *six months* since BDSI's last document production, and the last time BDSI produced documents of its *own* was in November of last year. Aquestive has reasonably and repeatedly attempted to move discovery forward; indeed, Aquestive has substantially completed its own production. But rather than cooperate in discovery, BDSI has offered only resistance and delay, with only hollow and even broken commitments to produce. Aquestive is left with no recourse but to seek relief from the Court.

II. RELEVANT FACTS

The complaints in these cases allege that BDSI infringes Aquestive's U.S. Patent No. 8,765,167 (Ex. A, "the '167 Patent") by making (or directing the making of), using, offering to sell, and selling its BUNAVAIL® and BELBUCA® buccal film products within the United States. The parties have exchanged preliminary infringement and invalidity contentions, and claim construction has been fully briefed since mid-December 2021. Aquestive has requested discovery into various aspects of the accused products, including development, manufacturing, related regulatory processes, and commercialization and marketing, among others.

Aquestive served its first set of RFPs (Nos. 1–12) in May 2021 (in the 505 matter) and

[1] The Requests for Production ("RFPs" or "requests") at issue, and BDSI's responses thereto, significantly overlap, and as such, for efficiency and for the Court's convenience, Aquestive submits a single memorandum applicable to motions to compel discovery in both Civil Action Nos. 19-cv-00505 ("the 505 matter") and 15-cv-00350 ("the 350 matter").

June 2021 (in the 350 matter), *see* Exs. B–C, and Aquestive served its second set (Nos. 13–55) in November, *see* Exs. D–E.[2] Together with generic objections that failed to indicate whether BDSI would withhold documents on the basis of those objections, *see* Exs. F–I, BDSI has made only limited document productions:

- In July 2021, BDSI produced a limited set of records it had submitted to the FDA relating to the new drug applications ("NDAs") for the accused products. The metadata for those records indicate that the documents came from ***a single folder*** (i.e., "NDA207932" for BELBUCA, "NDA105637" for BUNAVAIL).

- In August 2021, in tandem with its preliminary invalidity contentions, BDSI produced several publicly available references and alleged prior art, followed by the production of a single public document in September.

- On November 8, 2021, BDSI produced a sample of batch records for the accused products.[3]

- On January 23, 2022, BDSI produced documents purportedly maintained by third-party manufacturer ARx, LLC, but under BDSI's control.

The January 23, 2022 production was BDSI's last production in either case. Aquestive has repeatedly corresponded and conferred with BDSI regarding deficiencies in its document production. *See* Declaration of Jamie Lucia ("Lucia Decl.") ¶¶ 18–19, 21, 27; Exs. J, O, Q, Y. BDSI has strung Aquestive along each time with empty promises and months of delay. *See, e.g.*, Ex. T at Mar. 8, 2022 Email from W. Proctor (agreeing "to proceed promptly with discovery").

Receiving nothing from BDSI, Aquestive also served a third-party subpoena on BDSI's manufacturer, ARx, LLC, in January 2022. *See* Ex. BB. In February, ARx, represented by the same counsel for BDSI, provided boilerplate objections and offered to meet and confer. *See* Ex. CC. But ARx was unwilling to identify any documents for production, produced nothing, and

[2] Aquestive served a third set of RFPs on June 9, 2022. That set is not directly at issue here.
[3] "Batch records" document certain details about identified batches of drug products, which records are made available for review by the FDA. *See* 21 C.F.R. § 211.180(a).

ultimately moved to quash the subpoena.

Consistent with Local Civil Rule 7.1(c), Aquestive met and conferred with BDSI and ARx on February 10, 2022, with follow-up calls on March 1, 4, and 11, 2022, and subsequent correspondences. Lucia Decl. ¶¶ 14, 18–19, 23–25; Ex. DD. Throughout that colloquy, BDSI's counsel indicated it would identify additional responsive documents; and at one point BDSI's counsel represented that it had located a new repository of responsive documents within BDSI. Lucia Decl. ¶¶ 20. BDSI's counsel further indicated they were not interested in a drawn-out dispute and that they would "at least begin the fight if there's going to be a fight" over the extent of BDSI's further discovery obligations. *See* Lucia Decl. ¶ 21; Ex. Y (describing the meet and confer). Following BDSI's counsel's assurances that it would work in good faith to identify and to produce documents from both BDSI and ARx, Aquestive withdrew its subpoena to ARx and ARx withdrew its motion to quash, without prejudice to Aquestive's ability to serve a new subpoena. *See* Lucia Decl. ¶ 20.[4]

Far from bringing any discovery dispute to a prompt head, BDSI sat silent for months. Once prompted for an update, BDSI offered only inapposite objections to some requests, while still entirely failing to address others. Ex. X, June 9, 2022 Email from K. Freeman; *see also* Ex. Y, June 27, 2022 Letter from J. Lucia to K. Freeman. BDSI followed up to state, without support, that it has *not* "refused to produce" documents and cited vague efforts to collect some documents (still with no comment on others). Ex. Z, July 6, 2022 Letter from K. Freeman to J. Lucia. Another month has passed, and BDSI has offered nothing. No production; no timeline for production; no proposal; not even a status update. Aquestive has no choice but to seek the Court's intervention to compel BDSI to comply with its discovery obligations.

[4] Aquestive is concurrently re-issuing its subpoena to ARx.

III. ARGUMENT

Aquestive has propounded reasonable requests for production targeted at key issues in this case. BDSI's production to date has been perfunctory, and its responses to Aquestive's efforts to move discovery forward have been as baffling as they are nakedly dilatory.

A. Legal Standards

In a patent case, Federal Circuit law controls whether materials that relate to issues of substantive patent law, such as infringement or validity, are discoverable, but the law of the regional circuit applies to issues not unique to patent law, such as the procedure for discovery requests. *In re Queen's Univ. at Kingston*, 820 F.3d 1287, 1291 (Fed. Cir. 2016); *Commissariat A L'Energie Atomique v. Chi Mei Optoelectronics Corp.*, 395 F.3d 1315, 1322 (Fed. Cir. 2005).

"Federal Rule of Civil Procedure 26 allows broad discovery, including 'any nonprivileged matter that is relevant to any party's claim or defense,' and the information sought 'need not be admissible . . . if the discovery appears reasonably calculated to lead to the discovery of admissible evidence.'" *Pentair Water Pool & Spa, Inc. v. Hayward Indus., Inc.*, No. 5:11-CV-459-D, 2012 WL 6608619 (E.D.N.C. Dec. 18, 2012) (quoting Fed. R. Civ. P. 26(b)(1)). The party opposing a motion to compel bears the burden to demonstrate why discovery should not be granted. *Silicon Knights, Inc. v. Epic Games, Inc.*, 917 F. Supp. 2d 503, 533 (E.D.N.C. 2012), *aff'd*, 551 F. App'x 646 (4th Cir. 2014).

B. BDSI Should Produce Internal Documents Relating to the Manufacturing Process and Relationships with Third Parties

Aquestive requested that BDSI produce materials pertaining to BDSI's manufacturing and quality control mechanisms relating to the accused products. *See, e.g.*, Exs. B–E at RFPs 4–11,

13–14, 16–18, 46, 48–49.[5] Aquestive also requested that BDSI produce materials pertaining to BDSI's interactions with third parties, such as the manufacturers of BDSI's film products. *See, e.g.*, Exs. D–E at RFPs 15, 42–49. BDSI refuses to produce a trove of responsive materials.

These requests bear on central issues in this case. The precise details of the manufacturing process for the accused products is particularly important here, where the asserted claims of the '167 Patent specifically require, for example, that the claimed film be "formed by a controlled drying process." *E.g.*, Ex. A '167 Patent 41:12–13; *see ArcelorMittal Atlantique et Lorraine v. AK Steel Corp.*, 908 F.3d 1267, 1276 (Fed. Cir. 2018) ("In view of the claim language, the claimed thermal treatment process step . . . is of significant consequence to the infringement analysis."). And BDSI's instructions to manufacturers, among other communications with third parties and the related circumstances, bear directly on Aquestive's inducement claims. *E.g.*, Compl.[6] ¶ 68; *see DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc in relevant part) (noting inducement requires "specific intent to encourage another's infringement"); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1335 (Fed. Cir. 2016) (noting inducement can be proven by "circumstantial evidence").

BDSI has produced a sample of its batch records for the accused products, but BDSI possesses numerous other responsive records. For example, the batch records themselves cite a variety of documents that appear to bear on the details of the manufacturing process.[7] Moreover, BDSI's employees, and those of BDSI's manufacturer (ARx), surely maintained lab notebooks,

[5] The groupings and descriptions of Plaintiffs' RFPs are not an admission as to the limit of the underlying RFPs but are exemplary in nature as to the types of records Plaintiffs expect are under the possession, control, or custody of BDSI.

[6] References to "Compl." are to paragraphs in both the First Amended Complaint in the 350 matter (D.E. 76) and the Complaint in the 505 matter (D.E. 1).

[7] Specifically, they refer to various procedural requirements that BDSI's manufacturer uses and refers to as [redacted] documents.

presentations, minutes from strategy sessions, or other documentation of their development efforts that would not be reflected in the batch records prepared for FDA inspection. BDSI has objected to producing any such documents, resting on the allegation that they are not regularly provided to the FDA and so are not discoverable here. Ex. X; Ex. Z at 1–2. And it rested on that objection even as it vaguely indicated, *weeks ago*, that it would have a "proposal for possible discovery of [its manufacturer's] documents soon." Ex. Z at 2.

Even if true, it is of no moment that these materials are not produced to the regulatory agency responsible for evaluating the safety and efficacy of the accused products. This is a patent-infringement litigation in district court. Aquestive's requests fall squarely within the scope of discoverable subject matter, and BDSI should be compelled to produce all responsive materials.

C. BDSI Should Produce Internal Documents Relating to the Development of the Accused Products

Aquestive propounded numerous requests relating to BDSI's decision to develop the accused products, as well as BDSI's actual development efforts. *See, e.g.*, Exs. B–E at RFPs 7, 10–11, 13–15, 33, 48–49. To date, however, BDSI has not produced any internal documents regarding its decision to develop the accused products or of its actual development process. BDSI asserts that gathering such documents "has proven considerably more of an undertaking than originally expected," Ex. Z at 2, but it offers no indication whatsoever of what has been done so far, when a production can be expected (if at all), and, critically, why BDSI did not begin to collect and to produce on a rolling basis such responsive documents *when they were initially requested*.

As discussed above, Aquestive has alleged that BDSI has induced infringement of the '167 Patent, including via its instructions to manufacturers. Compl. ¶ 68. Aquestive has also alleged that BDSI's infringement of the '167 Patent was willful. Compl. ¶¶ 6, 61. And BDSI has

contended that the '167 Patent is invalid as obvious. BDSI Countercompl. (350 matter)[8] ¶ 26; BDSI Countercompl. (505 matter)[9] ¶ 25. Evidence relating to a defendant's decision to develop a drug is regularly considered as part of inducement and willfulness analyses. *See, e.g.*, *In re Rosuvastatin Calcium Pat. Litig.*, 703 F.3d 511, 527 (Fed. Cir. 2012); *Monsanto Co. v. E.I. Dupont De Nemours & Co.*, No. 4:09CV00686ERW, 2010 WL 5069908, at *4 (E.D. Mo. Dec. 7, 2010); *Warner-Lambert Co. v. Apotex Corp.*, No. 98 C 4293, 2001 WL 1104618, at *4 (N.D. Ill. Sept. 14, 2001), *aff'd,* 316 F.3d 1348 (Fed. Cir. 2003). Evidence regarding BDSI's evaluation and development of possible vehicles for the active ingredients in the accused products could also bear on objective indicia of non-obviousness, such as evidence of competitors' plans to copy the invention of the '167 Patent. *See, e.g.*, *Bayer Pharma AG v. Watson Lab'ys, Inc.*, 874 F.3d 1316, 1328 (Fed. Cir. 2017); *Par Pharm., Inc. v. Hospira, Inc.*, 420 F. Supp. 3d 256, 279 (D. Del. 2019), *aff'd,* 835 F. App'x 578 (Fed. Cir. 2020) (considering both sides' "lengthy development efforts with repeated failures" as indicator of non-obviousness).

Once again, BDSI has refused to timely participate in discovery. Instead, BDSI's production regarding the development of the accused products appears limited to its NDA filings. But the development process started well before the NDA filing—for example, the Investigational New Drug application for BEMA Buprenorphine was filed in 2005. BDSI has not produced a single internal record from that time period. Aquestive is entitled to discovery on the development of the accused products, and BDSI should be compelled without further delay to produce documents in response to Aquestive's reasonable and proportionate requests to that effect.

[8] References to "BDSI Countercompl. (350 matter)" are to the counterclaim portion of BDSI's answer and countercomplaint in the 350 matter (D.E. 81).
[9] References to "BDSI Countercompl. (505 matter)" are to the counterclaim portion of BDSI's answer and countercomplaint in the 505 matter (D.E. 27).

D. BDSI Has Not Produced Electronically Stored Information

The parties agreed on a search protocol for electronically stored information as part of the Stipulated Order Governing Electronic Discovery (D.E. 60, 505 matter) in July 2021. Over approximately four months (November 2021 to March 2022), Aquestive and BDSI negotiated over search terms. *See* Lucia Decl. ¶ 18. When the parties met and conferred over BDSI's outstanding discovery in March, counsel for BDSI expressed optimism that the production of electronically stored information would at least partially resolve many of the other disputes. Lucia Decl. ¶ 19; *see also* Ex. R (noting that BDSI "will move forward with review *and production*." (emphasis added)). BDSI has not provided any update as to general status of its productions, and not even a date when Aquestive might approximately expect a production. Lucia Decl. ¶ 26. BDSI should be compelled to produce all non-privileged documents responsive to Aquestive's proposed search terms, as modified and agreed to by Aquestive and BDSI without further delay.

E. BDSI has Failed to Produce any Documents Responsive to Other Categories

Commercial Market—Aquestive propounded several requests pertaining to the commercial market for the accused products. *See, e.g.*, Exs. D–E at RFPs 33–34, 37–40, 53. During a meet and confer, BDSI's counsel represented that such documents would be produced, but BDSI has not produced a single financial or marketing document. Aquestive is entitled to a damages award for BDSI's past and continued infringement; documents responsive to these requests are clearly relevant and proportional to the needs of the case. *See, e.g.*, *Commonwealth Sci. & Indus. Rsch. Organisation v. Cisco Sys., Inc.*, 809 F.3d 1295, 1302 (Fed. Cir. 2015) (finding damages theories without detailed market information "insufficiently reliable")

Organizational Charts and Operational Details—Aquestive requested that BDSI

produce "[a]ll organizational charts and other documents showing the past and present organizational and operational structure of Defendant since 2012, including all divisions, direct and indirect parents and subsidiaries, entities owned or controlled by Defendant, affiliates, predecessors, or successors in interest, and the identities of any officers, employees, and representatives, such as, without limitation, department officer/employee organizational charts." Ex. D–E at RFP 41. BDSI has not done so.

The requested information regarding the corporate structure is relevant at least to damages issues. *See, e.g.*, *Stambler v. Amazon.com, Inc.*, No. 2:09-CV-310 DF, 2011 WL 10538668, at *8 (E.D. Tex. May 23, 2011); *Funai Elec. Co. v. Orion Elec. Co.*, No. 01CIV.3501(AGS)(JCF), 2002 WL 1808419, at *6 (S.D.N.Y. Aug. 7, 2002). The requests are also relevant to the issue of BDSI's state of mind (such as regarding willfulness or inducement) as well as to identifying individuals with relevant information and providing context for the roles of personnel referenced in the limited materials BDSI has produced already.

Records related to BDSI's patents or patent applications—The FDA's Orange Book lists various patents related to both accused products, and some of those patents have been the subject matter of litigation. *See, e.g.*, *BioDelivery Scis. Int'l, Inc. v. Alvogen PB Rsch. & Dev. LLC*, No. CV 18-1395-CFC, 2021 WL 6691753 (D. Del. Dec. 20, 2021). BDSI's patents related to the accused products are relevant to infringement and validity, yet BDSI has failed to produce a single document responsive to requests for this information. *See, e.g.*, Exs. D–E at RFPs 19, 20.

Public statements concerning the accused products—Except for certain documents within the NDA folders identified, BDSI has not produced any public statements about either accused product. Similar to the items above, such statements are informative as to both the infringement of those products and any liability for that infringement. *See* Exs. D–E at RFP 53.

F. BDSI's Flawed Objections Do Not Excuse its Stonewalling

BDSI's written objections cannot rescue it from its failure to participate in discovery. Proper objections must "state with specificity the grounds for objecting to the request, including the reasons." Fed. R. Civ. P. 34(b)(2)(B). And objections "must state whether any responsive materials are being withheld on the basis of that objection." Fed. R. Civ. P. 34(b)(2)(C); *see also Silicon Knights, Inc.*, 917 F. Supp. 2d at 533 (compelling discovery where a party "failed to articulate any specific objection . . . and therefore has waived any legitimate objection it otherwise could have raised").

BDSI's responses and objections miss both marks. In lieu of specificity, BDSI's responses repeat the same generic refrain and completely fail to indicate whether it will produce anything. *See* Exs. F–I; *Mainstreet Collection v. Kirkland's, Inc.*, 270 F.R.D. 238, 240 (E.D.N.C. 2010) ("Mere recitation of the familiar litany that an interrogatory or a document production request is overly broad, burdensome, oppressive, and irrelevant does not suffice as a specific objection." (quotations omitted)). BDSI has waived its ability to rely on its written objections. Although BDSI's objections include now clearly a meaningless offer to meet and confer regarding the "scope" of the requests, BDSI has also even improperly refused to identify documents that it would produce in response to Aquestive's requests.

IV. CONCLUSION

For at least the reasons given above, the Court should issue an order granting Aquestive's motion and ordering BDSI to: (1) produce the documents requested in Aquestive's RFPs; (2) produce ESI pursuant to the agreed-upon search terms; (3) produce the documents within ten days; and (4) identify a date certain by which it will substantially complete its document productions that is no later than 30 days from entry of the Court's Order.

Date: July 28, 2022

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